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EXAMINER

WRIGHT, SONYA N

ART UNIT

PAPER NUMBER

1626

DATE MAILED: 06/12/2003

18

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/530,807

Applicant(s)

LOUIS ET AL.

Examiner

Sonya Wright

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 45-57 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 45-57 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other:

DETAILED ACTION

This Office Action is in response to Applicant's amendment filed 4-7-03. Claims 46-48 have been amended. Claims 49-57 have been added.

The written description rejection under 35 U.S.C. 112 1st in the Office Action mailed 12-31-02 is moot in view of the restriction requirement mailed 1-6-03.

The enablement rejection of "prevention" under 35 U.S.C. 112 1st in the Office Action mailed 12-31-02 is overcome with Applicant's amendment. The rejection over lack of enablement to conclude that the instant compounds could reasonably be expected to treat all cardiovascular system diseases, all kidney diseases, most all cardiovascular diseases, and all abnormal adrenal gland secretion disorders has been maintained for the reasons of record.

The rejection under 13 U.S.C. 112 2nd paragraph has been overcome with Applicant's amendments.

Election/Restrictions

Applicant's election with traverse of the compounds drawn to formula II wherein W is optionally substituted C5-C7 cycloalkyl; -CHR₁R₂, where R₁ and R₂ are independently selected from hydrogen, optionally substituted C1-C6 alkyl, optionally substituted C3-C7 cycloalkyl and optionally substituted aryl; Z is imino; X is O; and Y is optionally substituted C2-C3 alkylene in Paper No. 17 is acknowledged. The traversal is on the ground(s) that the Examiner has grouped the claims as being directed to compounds whereas the claims are directed to methods of treatment pursuant to an election in response to a previous restriction requirement. In addition, the compounds

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defined in the claims have a heteroaryl ring wherein X is O or S and Y is optionally substituted C2-C3 alkylene group as a common structural element as opposed to the variables R', R1, R2, X, W, Y, and Z as stated by the Examiner. Further, it appears from the Examiner's groupings that the "optionally substituted C5-C7 cycloalkyl" variable for W is substantially a different group from CHR1R2. However, Applicant points out that the C5-C7 cycloalkyl group corresponds to a CHR1R2 group where R1 and R2 are linked to form the C5-C7 cycloalkyl group, e.g., formulas III, IV and V which are subgroups of formula II. This is not found persuasive because although the claims are directed to methods of treatment, the claims have been grouped as in a compound claim because the Examiner must perform a structure search for compounds of similar structure and use. The compounds defined in the claims have a heteroaryl ring wherein X is O or S and Y is optionally substituted C2-C3 alkylene as a common structural element, however, the variables embrace a large number of compounds. Applicant points out that the C5-C7 cycloalkyl group corresponds to a CHR1R2 group where R1 and R2 are linked to form the C5-C7 cycloalkyl group. However, the claim does not state that R1 and R2 are linked to form the C5-C7 cycloalkyl group, therefore, one would assume that the CHR1R2 group is a different group from C5-C7 cycloalkyl.

The following generic concept as depicted in claim 1 is identified for examination along with the elected embodiment: compounds drawn to formula II wherein W is C6 cycloalkyl substituted by hydroxyl and optionally consisting of additional substituents; Z is imino; X is O; and Y is optionally substituted C2 alkylene. The

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remaining subject matter of claims 45-57 is withdrawn from further consideration under 37 CFR 1.142(b) as constituting other patentably distinct inventions.

Claim Objections

Claims 45-57 are objected to for containing non-elected subject matter. It is suggested that Applicant limit the claims to the generic concept identified supra to overcome this objection.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 45-57 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

For rejections under 35 U.S.C. 112, first paragraph, the following factors must be considered (In re Wands, 8 USPQ2d 1400, 1404 (CAFC, 1988)):

- 1) Nature of invention.
- 2) State of prior art.
- 3) Level of ordinary skill in the art.
- 4) Level of predictability in the art.
- 5) Amount of direction and guidance provided by the inventor.
- 6) Existence of working examples.
- 7) Breadth of claims.

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8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

Nature of Invention

Claims 45-57 are directed to "the treatment of diseases of the central nervous system, cardiovascular diseases, glaucoma," and other diseases.

State of Prior Art

The prior art does not indicate which diseases the instant compounds are useful in treating.

Level of Ordinary Skill in the Art

It has not been shown in the specification that the testing protocol used is accepted in the art as being predictive of the alleged utility. The specification lacks enablement to support that the instant compounds could reasonably be expected to treat all cardiovascular system diseases, all kidney diseases, most all cardiovascular diseases, and all abnormal adrenal gland secretion disorders. There are a vast number of diseases, including diseases of the central nervous system and cardiovascular system, and glaucoma, and Applicant does not give support for treating all forms of these disorders. Therefore, the level of ordinary skill in the art is high.

Level of Predictability in the Art

The various forms of the diseases in claims 45-57 have different causative agents, involve different cellular mechanisms, and, consequently, differ in treatment protocol. Therefore, the art pertaining to the diseases in claims 45-57 remains highly unpredictable.

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Amount of Direction and Guidance Provided by the Inventor

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. Applicant gives limited guidance in pages 1-4 in their entirety; page 5, lines 1 and 2; and pages 15-30.

Existence of Working Examples

Applicant provides only 7 Examples, therefore, the specification does not support the full scope of the claims. In other words, Applicant does not support that the instant compound is useful in treating diseases of the central nervous system, cardiovascular diseases, glaucoma, " and other diseases as claimed in claims 45-57.

Breadth of Claims

The claims are extremely broad due to the vast number of diseases listed in claim 45.

Quantity of Experimentation Needed to Make or Use the Invention Based on the

Content of the Disclosure

Based on the unpredictable nature of the invention and state of the prior art and the extreme breadth of the claims, one skilled in the art could not use the claimed invention without undue experimentation.

Response to Arguments

Applicant's arguments filed 10-1-02 have been fully considered but they are not persuasive with regard to the rejection over lack of enablement to conclude that the instant compounds could reasonably be expected to treat all cardiovascular system

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diseases, all kidney diseases, most all cardiovascular diseases, and all abnormal adrenal gland secretion disorders. Applicant argues that in making a determination of enablement, the proper inquiry is whether one of ordinary skill in the art would be able to use the claimed invention without undue experimentation. Applicant provides information regarding the state of the art and the relationship between the various receptors and their therapeutic activities. However, the various forms of the diseases in claims 45-57 have different causative agents, involve different cellular mechanisms, and, consequently, differ in treatment protocol. Therefore, the art pertaining to the diseases in claims 45-57 remains highly unpredictable. Applicant gives biological information to show a nexus between the instant claims and the treatment of the diseases listed in claim 45. However, claim 45 contains proviso language excluding several diseases. Because several diseases were excluded in claim 45, one cannot assume that the biological information is predictive that the instant compound is useful in treating the remaining diseases in claim 45. It is suggested that Applicant limit claim 45-57 to the diseases which have been supported in the specification as being treatable by the instant invention. Support can be shown in the specification through experimental evidence and working examples.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sonya Wright, whose telephone number is (703) 308-4539. The examiner can normally be reached on Monday-Friday from 8:00 AM - 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph K. McKane, can be reached at (703) 308-4537. The Unofficial fax phone number for this Group is (703) 308-7922. The Official fax phone numbers for this Group are (703) 308-4556 or 305-3592.

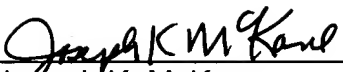
When filing a FAX in Technology Center 1600, please indicate in the Header (upper right) "Official" for papers that are to be entered into the file, and "Unofficial" for draft documents and other communications with the PTO that are not for entry into the file of the application. This will expedite processing of your papers.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [joseph.mckane@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees will not communicate with applicant via Internet e-mail where sensitive data will be exchanged or where there exists a possibility that sensitive data could be identified unless there is of record an express waiver of the confidentiality requirements under 35 U.S.C. 122 by the applicant. See the Interim Internet Usage Policy published by the Patent and Trademark Office Official Gazette on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-1235.

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Joseph K. McKane

Supervisory Patent Examiner

Group 1600

Sonya Wright

June 10, 2003